APR 2 3 2004

510(k) Summary

as required by 807.92

K03/661

1. Company Identification

Totoku Electric Co., Ltd.
300 Oya, Ueda-shi, Nagano-ken, 386-0192, JAPAN
Tel: 011-81-268-34-5484
Fax: 011-82-268-34-5565

2. Official Correspondent

Mikio Hasegawa (Mr.)
General Manager
Product Development Dept.

3. Date of Submission

May 26, 2003

4. Device Trade Name

5M Medical Flat Panel Display, ME511L

5. Common Name

Monitor, display, workstation, and others

6. Classification

Medical display is classified as Class I or II per 21 CFR 892.2050

7. Predicate Device

Totoku ME315L, 3 Megapixel Diagnostic Display, manufactured by Totoku Electric Co., Ltd. **(K030274)**. Comparison of the principle characteristics of the device, which is pertinent to clinical performance, is shown in Appendix 1.

8. Description of Device

ME511L is medical use display.

9. Intended Use

ME511L Medical Display is intended for use with Picture Archiving Communication Systems (PACS) for medical imaging applications by physicians.

K03166

10. Explanation of ME511L

ME 511L is monochrome LCD display.

ME511L (Model No. MDL2105A)

The specifications are shown in Appendix 2.

11. Compliance

ME511L complies with the following standards.

Medical Safety: UL2601-1, CSA No. 601-1, MDD/CE (EN60601-1), and TUV-GM

EMC: MDD/CE (EN60601-1-2), FCC-A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 3 2004

Mr. Mikio Hasegawa
General Manager
TOTOKU ELECTRIC CO., LTD,
MM Company, Design Group
300 Oya, Ueda,
Nagano 386-1092
JAPAN

Re: K031661
Trade/Device Name: 5M Medical Flat Panel Display, ME511L
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: February 3, 2004
Received: February 5, 2004

Dear Mr. Hasegawa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (If known): Not known K031661

Device Name: 5M Medical Flat Panel Display, ME511L

Indications for Use:

ME511L Medical Display is intended for use with Picture Archiving Communication Systems (PACS) for medical imaging application by physicians.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use

(Optional Format 1-2-96)

David A. Lippman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031661